K000860

JUN 3 0 2000

510(k) Summary

Futura Safety Syringe
Medisys PLC

Prepared March 15, 2000

Product Name: Futura Safety Syringe

Manufacturer: A Commercial Manufacturing site has not been selected.

Generic Name: Piston syringe with needle

Classification Name: Piston Syringe with needle

Contact Person: Sheila W. Pickering Ph.D.
2081 Longden Circle
Los Altos, California 94024
Telephone/Fax 650 969 6114

A. Legally Marketed Predicate Device

The Futura device is substantially equivalent to the following predicate devices with regard to device features, specifications, and intended use.

Sponsor	Predicate Device
New Medical Technology, Ltd.	NMT Safety Syringe
Retractable Technologies, Inc.	VanishPoint Syringe

B. Device Description

The Futura Safety Syringe is a 3cc piston type hypodermic syringe with an automated needle retraction system. It is a sterile, non-toxic, non-pyrogenic, retractable syringe designed to provide a safe and reliable method for intramuscular and subcutaneous injection of drugs and/or fluids while helping to provide protection from accidental needlestick.

Futura has an integral hypodermic needle available in 5/8", 1", and 1-1/2" lengths with needle gauges of 21G, 23G, 25G, 26G, 27G and 28G. Indications for use, dimensions, materials and operation are substantially equivalent to the predicate devices, i.e. the NMT Safety Syringe™ and Retractable Technologies' VanishPoint™ syringes.

C. Intended Use

The device is intended to be used for subcutaneous and intramuscular uses.
The Futura Safety Syringe is designed to provide a safe and reliable method of injecting medication and fluids into patients and also helps to protect the user from potential needlesticks. The Futura Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle safely inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retracting mechanism.

D. Substantial Equivalence

The following tables show the basis for substantial equivalence

	Predicate Devices		Submission Device	SE
Product Name (K number)	New Medical Technology NMT Safety Syringe K982431	Retractable Technologies VanishPoint Syringe K946219	Medisys Futura Safety Syringe	
Intended Use	The device is intended to be used for subcutaneous and intramuscular uses. The function of the NMTSafety Syringe is to provide a safe and reliable method of injecting medication into a patient that also protects the user from potential needlesticks The Futura Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retracting mechanism.	To retract and contain the contaminated needle after injection and render the syringe inoperable for further injections.	The device is intended to be used for subcutaneous and intramuscular uses. The function of the Futura Safety Syringe is to provide a safe and reliable method of injecting medication into a patient that also helps to protects the user from potential needlesticks The Futura Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle safely inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retracting mechanism	Yes
Users/Site of Use	Hospitals, clinics, laboratories	Hospitals, clinics, laboratories	Hospitals, clinics, laboratories	Yes

	Predicate Devices		Submission Device	SE
Product Name (K number)	New Medical Technology NMT Safety Syringe K982431	Retractable Technologies POP-N-LOCK Syringe K946219	Medisys Futura Safety Syringe	
Syringe type	Not provided in labeling	Plunger, antistick with hypodermic needle	Plunger, antistick with hypodermic needle	Yes
Volume	3cc	3cc –40M	3cc	Yes
Length of barrel and hub	Not provided in labeling	3.47 inches	4.19 inches	Yes
Diameter	Not provided in labeling	0.40 inches	0.42 inches	Yes
Materials	Not provided in labeling	Polypropylene rubber, stainless steel, epoxy, lubrican	Polypropylene rubber, stainless steel, epoxy, lubricant	Yes
Available needle gauge sizes	20 and 25G 1 and 1½ in	25G, ½ in 22G, 1½ in 23G, 1 in. 22G, 1in. 21G, 1½ in	28, 5/8 in 27, ½ in 26,1 and 1½ in 25, 1 and 1½ in 23, 1 and 1½ in 21, 1 and 1½ in	Yes
Needle cover color	Not provided in labeling	Colorless	Colorless	Yes

E. **Performance Data**

Design verification testing was conducted to confirm that the device met all functional specifications and applicable standards. Also, a simulated use evaluation with healthcare professionals demonstrated that the Futura device was substantially equivalent in performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Medisys PLC
C/O Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultant
for Medisys PLC
2081 Longden Circle
Los Altos, California 94024

Re: K000860
Trade Name: Futura Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: May 23, 2000
Received: May 30, 2000

Dear Dr. Pickering:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA Submission Cover Sheet

510(k) Number (if known): Not applicable K 000860

Device Name: Futura Safety Syringe

Indications For Use:

The device is intended to be used for subcutaneous and intramuscular use.

The function of the Futura Safety Syringe is designed to provide a safe and reliable method of injecting medication and fluids into patients and also helps to protect the user from potential needlesticks.

The Futura Safety Syringe functions as a conventional hypodermic syringe except for its ability to retract the contaminated needle safely inside the syringe immediately after the completion of the patient injection. Complete delivery of the syringe contents activates the retracting mechanism.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000860

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21CFR 801)